Saliwell GenNarino

Clinician Information

SALIWELL LTD.
MEDICAL SYSTEMS

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Overview

Thank you for choosing Saliwell GenNarino for the treatment of dry mouth. Saliwell Ltd. was established in 2003 with the aim of finding the most effective treatment for xerostomia. The Saliwell solution is the result of almost 20 years of research by Saliwell founders, followed by an extensive multinational research effort by leading academic and industrial groups from all over Europe.

Dry mouth is not a 'killer' disease; yet, it can impair quality of life and oral health significantly, not only by the constant discomfort of mouth dryness, but also by inducing difficulties in swallowing, chewing and speaking, increased dental caries rate, and bad breath.

The salivary glands can increase their secretion several folds from the basal level upon stimulation of their nerves. The Saliwell solution stimulates nerves associated with the salivary glands, which are responsible for activating the glands and generating saliva.

The company's extensive research resulted in an innovative, state-of-the-art device targeted at stimulating salivary gland function by electrostimulating their associated nerves (mainly the lingual nerve). The system consists of an intra-oral **removable device** named Saliwell GenNarino and a personal remote control. Saliwell GenNarino is a noninvasive salivary gland electrostimulator embedded inside a mouth-guard-like appliance that can be inserted and removed at will. This intelligent device contains a built-in power source, stimulation electrodes and a microprocessor that operates accurately and independently. Moreover, the device significantly reduces patient expenses for dry mouth therapeutic medication, and prevents resulting complications (for example, rampant caries and oral mucosal diseases).

In a series of clinical trials conducted in several leading medical centers, Saliwell GenNarino has proved to be highly efficient.

Main Features and Benefits

- Increases natural secretion of saliva[1]
- Self-contained unit with built-in microprocessor and power sources
- Lasts up to one year before replacement[2]
- Device is switched on and off by the personal remote control
- Induces no known side effects
- Suitable for most dry-mouth patients

This document is designed to acquaint the clinician with Saliwell GenNarino for dry mouth treatment. It includes a description for case selection, treatment, and recommended maintenance procedures.

For more information about dry mouth, see

[1] Increase in saliva secretion varies as a result of the patient's condition, more specifically the residual capacity of the salivary glands.
[2] The device's lifetime varies from one patient to another due to the selected stimulation intensity, frequency of use, and specific oral conditions.

Appendix A: About Dry Mouth. You may also visit our website www.saliwell.com or send an email to service@saliwell.com.

ISO Standardization

Saliwell GenNarino has been subjected to intensive biocompatibility tests according to the requirements of the ISO series of standards, and has received ISO 13485 standardization and certification.

Saliwell's GenNarino system is an active device for non-invasive, short-term applications. According to Annex IX, Rule No. 5 and especially Rule No. 9 of EC-Directive 93/42/EEC, the intra-oral product is classified as a Medical Device Class IIa; the external personal remote control unit is classified as Class I according to Rule No. 12.

Classification (according to the EN IEC 60601-1):

- Internal Powered Electrical Medical Device
- BF type (degree of protection against electrical shock)
- IPX8 (degree of protection against ingress of water of the intra-oral device only)

CE 0197

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Saliwell GenNarino System

Saliwell GenNarino operation is based on the application of stimulating signals to the nerves associated with the salivary glands to enhance natural saliva secretion. This is the most efficient method for relieving xerostomia.

Saliwell GenNarino is a noninvasive solution in which the stimulation electrodes are embedded inside a mouth-guard-like device (see Figure 1) that can be inserted and removed from the mouth as necessary. The stimulating electrodes protrude from the device. However, in order to prevent tissue injury, a space is provided between the flange from which they protrude and the tissue.

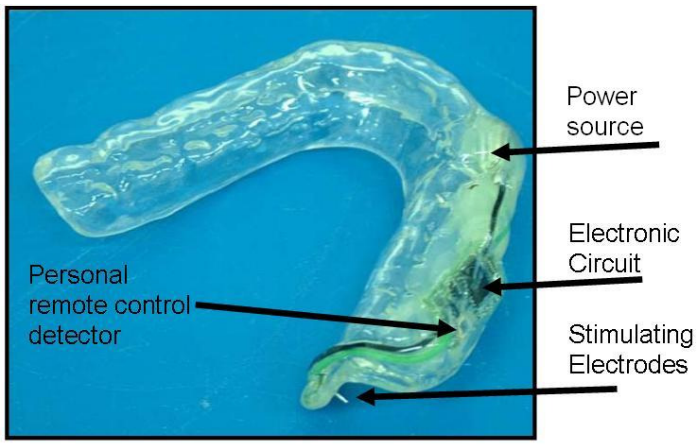

Figure 1: Mouth-guard-like option

Enhancing saliva secretion not only relieves dryness but also provides essential dental caries-fighting factors and other components that are critical for oral health.

Personal Remote Control

The personal remote control assists patients in switching Saliwell GenNarino on and off before inserting the device in the mouth and/or after it is removed. When working with the personal remote control, the front edge should always be aimed towards Saliwell GenNarino remote control detector at a distance of no more than 10 cm and in a shadowed environment.

The personal remote control has two buttons: one green and one black. When one of the buttons is pressed, Saliwell GenNarino detector blinks, and the electrostimulation switches on or off.

- The green button switches simulation ON
- The black button switches simulation OFF

Figure 2: Saliwell GenNarino personal remote control

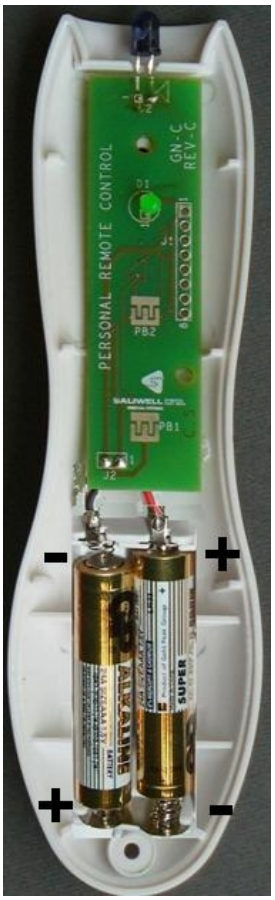

Figure 3: Saliwell GenNarino personal remote control battery compartment

Saliwell GenNarino Treatment

Success of the treatment with Saliwell's products depends on the patient's condition, needs and expectations. Saliwell GenNarino operation is based on the electrostimulation of the nerves that control saliva secretion and therefore is effective in patients with insufficient salivation.

Treatment Indications

- Subjective feeling of dry mouth (xerostomia)
- Salivary gland hypofunction
- Appearance of secondary conditions to salivary gland hypofunction that can occur in the absence of xerostomia complaints:
    - Rampant caries
    - Halitosis
    - Bad taste
    - Fungal infection
    - Burning mouth syndrome

Patients with no measurable salivary glands secretion are susceptible to a reduced response to Saliwell GenNarino stimulation.

Medical Precautions

The following medical conditions should be considered as a basis for special precautions prior to Saliwell GenNarino treatment:

- Use of a pacemaker
- Pregnancy
- Psychiatric or psychological disorders
- Epileptic disorder
- Involuntary muscle movement disorder (for example Parkinson's or Huntington's diseases)

It is recommended to consult a specialist in the specific area of the conditions listed above regarding concomitant use of Saliwell GenNarino.

Adverse Effects

Prolonged use of Saliwell GenNarino may cause irritation due to the mechanical pressure of the electrodes on the mucosa.

Procedures and Method of Use

Logistics

The proceedings of delivering a Saliwell GenNarino to your patient are:

1- Contact Saliwell via website (www.saliwell.com) or e-mail to sales@saliwell.com.

2- Saliwell sends to you a reply including a Quotation, an Order Form and a Laboratory Instructions Form, both to be completed by you.

3- Send to Saliwell:
   a. The completed Order Form via fax to + 972-77-353-4338
   b. The impression and the completed Laboratory Instructions Form, via mail or courier to Ortholine Dental Laboratory, 16 Giborey Israel, POB 8168, South Industrial Area Netanya 42504, Israel. **Important**: Protect properly the impression to avoid damage during transportation.

4- Your credit card will be charged after the receipt of the impression in Saliwell laboratory

5- The Saliwell GenNarino kit including your impression tray will be sent to you via registered airmail or courier (according to your instructions)

Note: All the forms can also be downloaded from our website

Taking the Impression

Impression of the lower dental arch is required for fabrication of Saliwell GenNarino.

Materials

1. Select a tray for the impression of the lower arch.
2. Make sure the tray extends to the distal and lingual aspect of the 3rd molar area (at least 1 cm away in each direction).
3. To ensure the stability of the impression, use polyether or polyvinylsiloxane.

Technique

1. Use either the two-stage impression technique (heavy body first and then light body) or the one-stage impression technique.
2. Apply adhesive on the impression trays based on the manufacturer's instructions.
3. **IMPORTANT**: Be sure to include in the impression no less than 3 mm tissue lingually to the lower third molars (whether they are present or missing).
4. If your patient wears a lower removable prosthesis it is advisable to use Saliwell GenNarino without the prosthesis in the mouth, in order to ensure intimate and stable contact of the electrodes with the tissue lingually to the lower third molar area. Thus, impression should be taken while the patients does not wear the prosthesis.

Figure 4: Impression

Disinfecting the Impression

Please, soak the impression in a disinfecting solution before it is packed and delivered. The disinfection process requires 10-minute soaking and air drying.

Receiving the Saliwell GenNarino kit

Saliwell GenNarino is custom made to fit the patient's mouth. Its fabrication takes up to 14 days, not including standard shipment. It is then shipped back to your office. The device is valid for one year.

Unpacking

Saliwell GenNarino kit includes:

- Saliwell GenNarino (turned off)
- Carrying case
- The personal remote control
- User Manual (for the patient)
- Guarantee card (see Appendix C: Saliwell Guarantee Card)
- Return envelope for the expired used device (in European countries)
- Summary sheet of clinician information

Setting Up and Delivering to the Patient

User Manual

Before delivering Saliwell GenNarino to the patient, read the User Manual.

Setting Up

Saliwell GenNarino is delivered switched off. During the appointment with your patient, activate it as follows:

- Press the green button of the personal remote control to switch Saliwell GenNarino on, pointing its front to the Saliwell GenNarino detector at a distance of 2-10 cm. If the device is working properly, the detector light blinks when it receives the command (this operation should be done in a dimmed environment).
- If during setup Saliwell GenNarino detector light does not respond to the personal remote control commands, consult the Troubleshooting section in the User Manual.
- For any further questions or problems contact the Saliwell Help Desk by sending an email to service@saliwell.com.

Adjustment and Delivery to the Patient

1. Disinfect Saliwell GenNarino with a sterile sponge or gauze and 70% alcohol.
2. Insert Saliwell GenNarino into the patient's mouth by gently pushing it with your fingertips over the teeth. First insert the side with the electrodes and then the other side.
3. If the patient reports discomfort, make fine adjustments by releasing stressful spots inside the device. Use a fit checker to locate the exact spot and a hand piece to remove a thin acrylic layer.
4. The electrodes length is adapted to the impression received by Saliwell, without hurting the tissue. If the patient feels that the electrodes prick the tisue, you may slightly shorten the electrodes using the high speed turbine **gently**. However, overtrimming the electrodes will annul the stimulating effect as the electrodes must definitely be in contact with the tissue. Thus, minimal shortening of electrodes, just to ensure they to not wound the tissue, should be performed.
5. Patients after radioptherapy to the head and neck and receiving bisphosphonates are at increased risk of developing osteonecrosis of the jaws. In those patients, special attention is warranted in order to avoid injuring the tissue by the device, especially the electrodes.

Caution: To prevent damages to the electronic circuit inside Saliwell GenNarino, avoid drilling in a 2 mm safety band surrounding the functional elements of the device: electronic circuit, electrodes, and batteries.

Instructions for Use

Advise your patient to use Saliwell GenNarino initially for ten minutes when he/she feels that the mouth is dry. Patients will learn to adjust the length of use (which can be as short as one minute) according to their needs.

Frequency of use also varies from patient to patient and typically ranges from twice to five times a day. Nighttime use is possible. However, it is not recommended to use the device more than once every hour.

For more information, see the User Guide.

Maintenance

Saliwell GenNarino should be washed with water after every use and kept in its Saliwell case. It is also recommended that the patient cleans the device once a day with soap. For more information, see the User Guide.

Recycling and discarding

Both Saliwell GenNarino and personal remote control should be handled in the European Community countries in accordance to the "Directive 2002/96/EC of the European Parliament and of the Council" dated 27 January 2003 on Waste Electrical and Electronic Equipment (WEEE). At the end of each product life time it should be mailed back to SALIWELL ISRAEL for proper recycling, using the envelope provided in the purchasing package, to:

Saliwell Ltd.
2 Hatamar St.
Harutzim 60917
Israel

Mailing fees were reimbursed already by a deduction from the purchasing payment.

Appendix A: About Dry Mouth

Saliva facilitates the patient's speech, taste, chewing, swallowing, digestion, and teeth protection. Insufficient saliva production may lead to xerostomia, which is the symptom of suffering from dry mouth.

Prevalence of Dry Mouth

Xerostomia is a common symptom that may affect at least one-tenth of the adult population. Oral dryness is more common among the elderly, and more common in women than in men. For more information about dry mouth visit www.saliwell.com or www.drymouth.info.

Etiology of Dry Mouth

Dry mouth is primarily caused by a compromised function of the salivary glands, often induced by:

- Medications
- Head and neck radiotherapy
- Autoimmune diseases, for example, Sjögren's Syndrome
- Anxiety states
- Diabetes
- HIV infection
- Other causes

Comprehensive information about medications that can potentially induce dry mouth can be found in Appendix B: Drugs Causing Dry Mouth and in www.drymouth.info.

Dry Mouth Diagnosis

Saliwell GenNarino is indicated for the treatment of dry mouth. The term “dry mouth” reflects two conditions that may or may not be related:

- Xerostomia - the individual's subjective sensation of dry mouth
- Hyposalivation - reduced salivary flow rate.

Anamnesis

It is recommended to record and document the following details:

- Patient's chief complaint
- Dental history (including xerostomia treatment)
- If the patient suffers from xerostomia, etiology and severity of the condition
- Patient’s expectations from the treatment with Saliwell device

- Evaluation of the patient's compliance with the Saliwell treatment

Oral Signs and symptoms related to Dry Mouth

Patients suffering from dry mouth may complain about any of the following symptoms:

- Decrease in the amount of the saliva
- Change in the texture of the saliva (foamy, viscous, ropy)
- Dry and/or cracked lips
- Burning mouth
- Swelling and/or pain of the salivary gland
- Frequent necessity of fluid intake when eating or when in bed
- Difficulty eating dry food, using dentures, swallowing, speaking, tasting food
- Bad breath or taste
- Waking up from sleep due to dry mouth

Some patients express no complaint of xerostomia despite suffering from hyposalivation. In these cases, the signs of salivary gland hypofunction may help you diagnose the condition. A patient suffering from the following conditions should be suspected of reduced salivation:

- History of rampant or cervical caries
- Halitosis
- Bad taste sensation
- Fungal infection
- Burning mouth

Xerostomia diagnosis

Several symptoms are reliable indicators of xerostomia. The following questionnaire may help you assessing your patient's condition:

- Do you have the need to do something to keep your mouth moist?
- Do you get out of bed at night to drink water?
- Do you have difficulties speaking due to lack of mouth lubrication?
- Do you have difficulties swallowing dry food?

Hyposalivation diagnosis

The diagnosis of hyposalivation is based on a simple in-office saliva flow rate measurement. The most common measurement method is Whole Saliva Collection, in which saliva is collected in a tube for at least 5 minutes after having nothing in the mouth for at least 90 minutes. The patient is asked to expectorate into the tube during the collection period, and to refrain from swallowing saliva. The tube is weighed prior and after saliva collection and the difference in weight (measured in grams) indicates the volume of saliva collected (in

milliliters). This volume is finally divided by the number of minutes during which saliva has been collected to obtain to flow rate value.

To obtain stimulated salivary flow rate, ask the patient to chew a piece of paraffin while collecting the saliva. Due to circadian variations in flow rate, repeated salivary collections should be performed at a similar time of the day.

The flow rate of saliva is a dynamic and variable parameter. The following table provides an indication of normally found salivary flow rates.

Table 1: Whole salive flow rates

	Normal Flow Rate	Abnormal Flow Rate
Unstimulated whole saliva	0.3-0.4 ml/min	<0.1 ml/min
Stimulated whole Saliva	1-2 ml/min	<0.5 ml/min

Appendix B: Drugs Causing Dry Mouth

Sensation of dry mouth may be caused by the intake of dryness-inducing medications. Of the most 50 prescribed medications in the US in 2003, 64% were xerogenic. Altogether, there are 1,800 drugs in 80 drugs classes which are known to have the side effect of inducing dry mouth. More information in www.drymouth.info. The xerogenic drugs belong to the following (and also other) drug categories.

ABUSIVE DRUGS
AIDS RELATEDTHERAPEUTIC AGENTS
ALZHEIMER'S DISEASE MANAGEMENT
ANALGESICS
ANAPHYLAXIS EMERGENCY KIT
ANOREXIANTS
ANTI-ARRHYTHMIC MEDICATIONS
ANTI-INFECTIVE AGENTS
ANTI-INFLAMMATORY AGENTS
ANTI-NEOPLASTIC AGENTS
ANTI-RHEUMATIC AGENTS
ANTI-ULCER AGENTS
ANTICHOLINERGICS & ANTISPASMODICS
ANTIHISTAMINES
ANTIHISTAMINES AND DECONGESTANTS
ANTIHYPERLIPIDEMIC AGENTS
ANTIHYPERTENSIVES
ASSISTED REPRODUCTIVE TECHNOLOGY
BENZODIAZEPENE ANTAGONIST
BLOOD MODIFIER
BRONCHODILATORS
CENTRAL NERVOUS SYSTEM STIMULANT
CERVICAL DYSTONIA TREATMENT
COLD AND COUGH PREPARATIONS
DERMATOLOGICAL PREPARATIONS
DIAGNOSTIC AIDS
DIARRHEA MEDICATIONS
DIGESTIVES
DIURETICS
ERECTILE DYSFUNCTION MANAGEMENT
GASTROINTESTINAL AGENTS
GENERAL ANESTHETICS
HEMORRHEOLOGIC AGENT
HORMONES
HYPERPROLACTINEMIC DISORDERS
HYPERTENSIVE EMERGENCY AGENT
HYPOTENSION MANAGEMENT
IMMUNOLOGIC AGENTS
LOU GEHRING'S DISEASE THERAP. AGENTS
MIGRAINE MANAGEMENT
MULTIPLE SCLEROSIS MANAGEMENT

MUSCLE RELAXANTS
NASAL DECONGESTANTS
NASAL INHALANTS
NAUSEA MEDICATIONS
NERVE AGENT POISONING TREATMENT
NUTRITIONAL SUPPLEMENTS
OPHTHALMIC PREPARATIONS
OPIOID ANTAGONISTS
OSTEOPOROSIS MANAGEMENT
PAGET'S DISEASE MANAGEMENT
PARKINSONISM DRUGS
PSYCHOTROPIC AGENTS
SEIZURE DISORDER MEDICATION
SLEEP AIDS
SMOKING CESSATION AIDS
SYMPATHOMIMETIC COMBINATION
TREATMENT OF ATTENTION
TREATMENT OF GAUCHER DISEASE
VASODILATORS

Appendix C: Saliwell Guarantee Card

SALIWELL LTD.
MEDICAL SYSTEMS

Saliwell GenNarino Guarantee Card

Serial number: ……

1. Saliwell Ltd. guarantee is for a 12 month period from the day the GenNarino system has left our laboratory, for any damage attributable to the fabrication.
2. Saliwell Ltd. guarantee is not valid in the following occasions:
2.1. Misuse of the Saliwell GenNarino system.
2.2. Maintenance which doesn't follow Saliwell instructions.
2.3. Breakage of the device or the electrode.
2.4. Damage which was caused by exposure to sun or heat.
2.5. Damage which was caused by exposure to active liquids (e.g. strong detergent, hypochlorite, acids, etc.)
2.6. Damage which was caused by high power, fall or neglect.
2.7. Damage which was caused by the clinician's handpiece during adjustment of the device.
3. A damaged device should be sent to our laboratories. The repair of the Saliwell GenNarino requires a new impression of the patient.

FORM : MN-01b